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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,064	10/31/2001	Carolyn Elizabeth Lister	01288.0016	4565

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

9

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/890,064

Applicant(s)

LISTER ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 20 May 2003, paper number 8.
2. Applicant has amended claims 1-9, 11, and 13-15. Claims 1-15 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

5. The objection to Applicant's specification is maintained; Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

### ***Claim Rejections - 35 USC § 112, second paragraph***

6. Claims 1-15 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

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- “gene” is unclear because a “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant’s intention, the language “a DNA of interest” is suggested. Or Applicant may recite the various components of the “gene” desired. All recitations of “gene” are also rejected. See claims 9, 10, 11, 12, 13 and 15, for example. The basis for this rejection is restated to emphasize that all recitations of this language are rejected.

In claim 1

- “embryo derived cells” (line 4) is unclear because the metes and bounds of the claim are not apparent; this would appear to encompass all cells of the plant.
- “a vector or direct DNA transfer” is unclear; how does a “vector differ from from direct DNA transfer?
- In claim 1, a step is missing—where does the transformation happen?
- “transformation “ (line 8) lacks antecedent basis.
- Furthermore, claim 1 is an incomplete method claims because the final step does not produce the recited final product
- “transformation “ (line 8) lacks antecedent basis.

In claim 4, “the embryos” lacks antecedent basis. Previous recitation is to “embryo cells”.

In claim 5,

- “embryos” lack antecedent basis
- “an active-T-DNA” is unclear. Active for what? No frame of reference is provided.
- “immediate” is unclear –what is the timeframe for “immediate?”

Claim 7 is missing an essential element—where is the transformation step? what is the transformed DNA?

- Furthermore, claim 7 is an incomplete method claims because the final step does not produce the recited final product, which is a transformed *Allium* genus plant.

In claim 7, (b) “cultures” lacks antecedent basis; a step seems to be missing here.

- In claim 7 (c) and (d), “embryos” lacks antecedent basis. “immature embryos” has been previous recited, however.

In claims 13 and 15, what does “modified” mean” with regards to an alliinase gene?

Applicant traverses, stating primarily that “modified” is to be given its ordinary meaning by one skilled in the art. For example , a modified alliinase gene can be

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a gene that over-expresses, temporally or spatially expresses, or has suppressed expression of its gene product”.

Applicant's traversal has been considered and is unpersuasive because the ordinary meaning of “modify” is to “change in form or function” (Webster’s Dictionary, 1994, page 762).

***Claim Rejections - 35 USC § 112, first paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The 35 USC 112.1 enablement rejection of 17 December 2002 is vacated and withdrawn in view of the 112.1 enablement rejection below.

Claim 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). the enablement issues are i) delivery of DNA by a vector or direct gene transfer, ii) “a

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modified alliinase” and “a modified gene involved in sulfur pathway assimilation or breakdown and as a result has altered levels of sulfur compounds”.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)):

*Nature of the invention.* The claims are drawn to method of transforming an Allium genus plant comprising the steps (a) delivering DNA into embryo cells, or embryo derived culture cells of the Allium genus plant via a vector or direct gene transfer to produce transformed plant material, (b) selecting the transformed plant material, (c) culturing and regenerating the transformed plant material, wherein the transformation is carried out with passage through a callus phase, where the Allium plant is transformed with a stain of Agrobacterium, where the Allium genus plant is an onion, where the embryos are transformed with a binary vector, where the embryos are inoculated with an Agrobacterium strain containing an active T-DNA immediately after isolation of the embryos, where the embryos are immature embryos, where the DNA of interest is a herbicide resistance gene, a bar gene, a glyphosate resistance gene, an antibiotic resistance gene, and a nptII gene. And to the method where the plant is transformed with a modified alliinase gene, to a transformed plant produced by the methods where the plant contains a modified gene involved in sulfur pathway assimilation or breakdown and as a result has altered levels of sulphur compounds.

*Even if Applicant were enabled, this would be enabled only to the extent of claims limited to a method of transforming an Allium genus plant, as described in the specification (page 5, line 11 through page 6, line 14). While the specification can provide clarification of elements which are known to one skilled in the art, essential steps and conditions not known to one of ordinary skill in the art are unpredictable, and must be recited in the claims.*

Applicant claims transformation by a vector or direct gene transfer. Applicant teaches transformation by Agrobacterium as described in the specification (page 5, line 11 through page 6, line 14). Agrobacterium and direct gene transfer differ in that direct gene transfer is a mechanical means to deliver DNA and Agrobacterium is a biological process and that the mechanism is quite different for the two. See Hansen et. al., Recent advances in the transformation of plants, Trends in Plant Science, volume 4, No 6, June 1999, pages 226-231, see pages 228, 229 and 230. . Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Applicant's response (page 11) asserts that "Applicant has carried out sufficient research to demonstrate that this (microparticle) method of wounding plants cells will not deliver the vector or DNA ...into a complete fertile plant."

Thus Applicant appears to assert that the claimed invention is not enabled.



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Applicant traverses, stating primarily that (p. 6) the lack of enablement rejection of the 17 December 2002 Office Action is improper for various reasons.

Applicant's traversal has been considered and is unpersuasive because this previous rejection has been vacated.

Applicant traverses, stating primarily that the teaching of the specification would be relatively easy for one skilled in the art to practice.

Applicant's traversal has been considered and is unpersuasive because no evidence of this is offered.

Applicant traverses, stating primarily that to demonstrate that the scope of claims 1-12 is sufficient for one skilled in the art to practice, Applicant represents that the technique is now being used by two commercial companies in the US to transform allium.

Applicant's traversal has been considered and is unpersuasive because the claims must be enabled as of the date of filing, 29 January 1999.

Applicant traverses, stating primarily that in as previously stated experience they have seen "two definite unpredicted resulting from ..transgenic events", citing a 2003 document.

Applicant's traversal has been considered and is unpersuasive because the claims must be enabled as of the date of filing, 29 January 1999.

*Re “a modified alliinase” and “a modified gene involved in sulfur pathway assimilation or breakdown and as a result has altered levels of sulfur compounds”.*

The skilled person would not be able to introduce a “modified gene” or a “modified alliinase” into cells of a plant, without guidance as to the nature of the “modification”.

What is “modified”? Is it a coding sequence, a regulatory sequence? Or does the modification involve coding sequences? Or regulatory sequences, or both? Is the modification a mutation? Does the modification involve insertions, or deletions, or rearrangements or combinations of these? Or is it a second-site regulatory mutant?

There are no working examples of any modified alliinase or any modified gene resulting in altered levels of sulfur compounds.

*Guidance in the specification & Predictability of the art.* The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). The art is such that the skilled person can introduce genes into plant cells but that transformation with a “modified” gene or “modified alliinase to produce a transformed plant containing a modified gene involved in sulfur pathways so as to result in altered levels of sulfur compounds”, without guidance as to what modifications to make to have the desired effect, would require undue experimentation. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

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In view of the breadth of the claims (any vector, any direct gene transfer, any Agrobacterium, any modification, a modified gene, modified alliinase, any alteration of sulfur compounds), the lack of guidance in the specification, the unpredictability of the art, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bidney, as discussed above.

Bidney teaches a method of transforming Allium plants comprising delivering previously manipulated DNA into embryos (page 4, line 12) via a binary vector (p 4, line 30), selecting transformed material (p 6, line 42), and culturing and regenerating transformed plants (p 3, line 9). Bidney further teaches the method using Agrobacterium (p 4, lines 16-32), onions (p 4, line 1), the use of immature embryos (p 4, line 10), Agrobacterium having a selectable marker (p 3, lines 23-29), herbicide

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resistance gene (p 3, 25-29), bar resistance, an antibiotic resistance gene and a nptII gene (p3 line 25). Bidney does not teach regeneration of embryogenic cultures with a callus phase. One of ordinary skill in the art would have been motivated to use embryos immediately after their isolation, because this would shorten the time needed for the overall process, and would make the process faster.

Nor does Bidney teach a method where embryos are inoculated immediately following their isolation. One of ordinary skill in the art would have been motivated to use embryos immediately after their isolation, because this would shorten the time needed for the overall process, and would make the process faster.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

#### *Remarks*

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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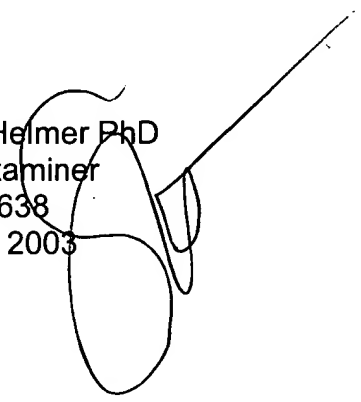
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

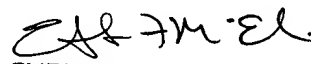
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Unit 1638  
August 1, 2003



  
**ELIZABETH F. McELWAIN**  
**PRIMARY EXAMINER**  
**GROUP 1800**